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| APPLICATION NO.            | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|----------------------------|----------------|----------------------|-------------------------|------------------|--|
| 10/035,918                 | 12/28/2001     | Rajiv Shah           | 047711-0293             | 2208             |  |
| 75                         | 590 03/10/2003 |                      |                         |                  |  |
| Irvin C. Harrington, III   |                |                      | EXAMINER                |                  |  |
| FOLEY & LARDNER 35th Floor |                |                      | PAK, YONG D             |                  |  |
| 2029 Century Park East     |                |                      |                         |                  |  |
| Los Angeles, CA 90067-3021 |                |                      | ART UNIT                | PAPER NUMBER     |  |
|                            |                |                      | 1652                    | - 7 ·            |  |
|                            |                |                      | DATE MAILED: 03/10/2003 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |  | Application No.                   | Applicant(s)   |                    |  |  |  |  |
|---|--|-----------------------------------|--|--------------------|--|--|--|--|
| Office Action Summary   |  |                                   | SHAH ET AL.  |                    |  |  |  |  |
|   |  | 10/035,918<br>Examiner            | Art Unit   |                    |  |  |  |  |
|   | omov nodon odminary  |                                   | 1652   |                    |  |  |  |  |
|   | The MAIL ING DATE of this communication  | Yong Pak on appears on the covers |  | ddress             |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply   |  |                                   |  |                    |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status |  |                                   |  |                    |  |  |  |  |
|   | Responsive to communication(s) filed o   | n                                 |  |                    |  |  |  |  |
| 2a)   | This action is <b>FINAL</b> . 2b)  | ☐ This action is non-fin          |  |                    |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |  |                                   |  |                    |  |  |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>  |  |                                   |  |                    |  |  |  |  |
| 4)⊠ Claim(s) <u>1-43</u> is/are pending in the application.   |  |                                   |  |                    |  |  |  |  |
|   | 4a) Of the above claim(s) is/are withdrawn from consideration.   |                                   |  |                    |  |  |  |  |
| •   | 5) Claim(s) is/are allowed.  |                                   |  |                    |  |  |  |  |
|   | Claim(s) is/are rejected.  |                                   |  |                    |  |  |  |  |
| · ·   | Claim(s) is/are objected to.   |                                   |  |                    |  |  |  |  |
| 8) Claim(s) <u>1-43</u> are subject to restriction and/or election requirement.   |  |                                   |  |                    |  |  |  |  |
| Application Papers  9) The specification is objected to by the Examiner.  |  |                                   |  |                    |  |  |  |  |
| •   | ne drawing(s) filed on is/are: a)  |                                   | ed to by the Examiner.   |                    |  |  |  |  |
|   | Applicant may not request that any objection   |                                   |  | 1).                |  |  |  |  |
|   | ne proposed drawing correction filed on  |                                   |  |                    |  |  |  |  |
|   | If approved, corrected drawings are require  |                                   |  |                    |  |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |  |                                   |  |                    |  |  |  |  |
| -   | der 35 U.S.C. §§ 119 and 120   |                                   |  |                    |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |  |                                   |  |                    |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |  |                                   |  |                    |  |  |  |  |
| 1   | <ol> <li>Certified copies of the priority documents have been received.</li> </ol>   |                                   |  |                    |  |  |  |  |
| 2   | 2. Certified copies of the priority documents have been received in Application No   |                                   |  |                    |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.  |  |                                   |  |                    |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |  |                                   |  |                    |  |  |  |  |
| a) ☐ The translation of the foreign language provisional application has been received.  15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |  |                                   |  |                    |  |  |  |  |
| Attachment(s)   |  |                                   |  |                    |  |  |  |  |
| 1) Notice   | of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO- ation Disclosure Statement(s) (PTO-1449) Paper | 4)                                | Interview Summary (PTO-413) Paper<br>Notice of Informal Patent Application (<br>Other: | No(s)<br>(PTO-152) |  |  |  |  |

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## **DETAILED ACTION**

Claims 1-43 are pending.

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-24, drawn to a method for formulating an enzyme comprising creating at least one mutated glucose oxidase gene, introducing each mutated glucose oxidase gene into separate expression vectors and screening the colonies for desirable properties, classified in class 435, subclass 440.
- II. Claims 25 and 43, drawn to an oxidase gene, classified in class 435, subclass 189.
- III. Claims 26-42, drawn to a method for formulating an enzyme comprising obtaining an organism with a glucose oxidase gene, altering the environment and screening for the enzyme, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Inventions (I and III) and (II) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case mutant glucose oxidase can be generated by random mutagenesis.

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The methods of Inventions I and III are patentably distinct because Invention uses mutant glucose oxidase made by recombinant methods and Invention III uses a microorganisms having a glucose oxidase gene that is mutagenized by altering the environment.

This application contains claims directed to the following patentably distinct species of the claimed invention: methods of detecting active glucose oxidase (claims 2 and 26), different methods of using sensors to detect active glucose oxidase (claims 10 and 35), different methods of extracting the enzyme (claim 11 and 35), different methods of purifying the glucose oxidase (claim 13 and 37) and different methods of mutagenizing the enzyme (1).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 10, 11, 13, 26, 35 and 37generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

March 5, 2003